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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,231

02/24/2004

Mark Gelfand

4491-2

1587

32488

7590

06/03/2008

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

06/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,231	Applicant(s) GELFAND ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 28-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-9-08, 2-27-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,8,10,14,15,24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 10, and 15 recite “high concentration”. The specification does not reasonably apprise one of ordinary skill in the art as to the meaning of “high”. See MPEP 2173.05(b).

Claim 8 recites “the catheter” which lacks proper antecedence.

Claim 14 is indefinite because it is unclear if the step of injecting contrast is positively recited because dependent claim 23 recites injecting contrast.

Claims 24 are indefinite because “the period of contrast” is defined as from injection until a 50% reduction of contrast (claim 24). However, a period of contrast would readily be understood to include a period in which contrast is present (i.e 40% or 25% of injection concentration).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5,8-12,14,16-19,22,25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Doty et al. Effect of Increased Renal Venous Pressure on Renal Function (“Doty”).

Doty discloses a method including the steps of increasing renal venous pressure by 30 mmHg above baseline including the substeps of injecting contrast (inulin) and inserting a catheter into a renal vein wherein renal functions are reduced as a result thereof.

Claims 1-6,8,9,10,14-20,22,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sterman et al. USPN 6699231 (“Sterman”).

Sterman disclose a method of protecting a kidney from an insult by reducing renal functions of the kidney due to increasing pressure in the renal vein (see col. 22 line 62 - col. 23 line 13, col. 24 line 63 – col. 25 line 16, col. 25 line 63 – col. 26 line 17). The method further comprises monitoring/adjusting pressure (col. 15 line 31- col. 16 line 10) and insertion of a balloon catheter to at least partially occlude the renal vein.

Regarding claims 10 and 24, Sterman discloses injection of contrast media (col. 4 lines 59- col. 5 line 1, col. 25 line 63- col. 26 line 17), the procedure may last up to four hours or longer (col. 5 lines 19-32), and the procedure could entail delivery and uptake of contrast agents in another region of the body while the renal vein is occluded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7,13,21,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. USPN 6699231 ("Sterman").

Sterman is described supra. Sterman teaches monitoring the pressure and adjusting the pressure by altering fluid volume during recirculation (col. 15 line 31- col. 16 line 10) and further a pressure control means (col. 15 lines 21-30), but fail to describe a step of increasing pressure by adjusting the balloon. However it would have been obvious to one of ordinary skill in the art to include the step of adjusting the balloon to adjust pressure because it is well known that pressure could be reduced, in the event of overpressurization, by deflating the occluding balloon. On the other hand, should the pressure drop, due to a leak about the occluding balloon, it would have been obvious to a skilled artisan to increase balloon pressure to fully occlude the vessel as desired by Sterman.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774